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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/531,874

04/19/2005

Ryuji Ueno

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EXAMINER

POLANSKY, GREGG

ART UNIT

PAPER NUMBER

1614

MAIL DATE

DELIVERY MODE

12/07/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/531,874

Applicant(s)

UENO, RYUJI

Examiner

Gregg Polansky

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) 10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 11-13 is/are rejected.
- 7) ☒ Claim(s) 3-9 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :4/19/2005, 2/14/2006, & 5/9/2007.

DETAILED ACTION

Status of Claims

1. Applicant's election without traverse of the species 13,14-dihydro-15-keto-16,16-difluoro-PGE₁, in the reply filed on 6/01/2007 is acknowledged. The Election of Species Requirement is thus deemed to be proper and is made Final.
2. Claims 1-13 are pending.
3. Claim 10 is withdrawn, from consideration because it does not read on the elected species. 37 CFR 1.142(b).
4. Claims 1-9 and 11-13 are presently under consideration.

Claim Objections

5. Claims 3-9 are objected to for the following informalities: the phrase "wherein said prostaglandin compound is 16-mono..." (Claim 3), and "wherein said prostaglandin compound is 13,14-dihydro..." (Claims 4-9), should be changed to "wherein said prostaglandin compound is a 16-mono..." and "wherein said prostaglandin compound is a 13,14-dihydro...", respectively (emphasis added). Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 2-9 and 11-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding Claim 2, the phrase "**general** formula" (emphasis added) renders the claim indefinite because the word "general" offers no probative value to the formula.

Claim 2 is drawn to the "method of Claim 1, wherein said prostaglandin compound is the compound as shown" in formula (I), wherein "A is $-\text{CH}_3$, or $-\text{CH}_2\text{OH}$, $-\text{COCH}_2\text{OH}$, $-\text{COOH}$ or a **functional derivative** thereof" (emphasis added).

Although derivatives are often used in the field to refer to compounds having the same or similar therapeutic activity and pharmacological core, the boundaries of these terms are not clearly defined in the specification or claims. Therefore, one skilled in the art would not be able to ascertain the metes and bounds of the claims. Applicants should recite those "derivatives" contemplated and not a mere wish or plan for obtaining the claimed chemical invention.

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claim 2 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. This is a Written Description rejection.

Claim 2 is drawn to the method of Claim 1, wherein said prostaglandin compound is the compound as shown in formula (I), wherein R_1 is a saturated or unsaturated bivalent lower or medium aliphatic hydrocarbon residue, which is unsubstituted or substituted with halogen, alkyl, hydroxy, oxo, **aryl or heterocyclic** group (emphasis added).

There is insufficient written basis for R_1 being an undefined aryl or heterocyclic group in the specification.

Regarding the requirement for adequate written description of chemical entities, Applicant's attention is directed to MPEP §2163. In particular, *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1568 (Fed. Cir. 1997), *cert denied*, 523 U.S. 1089, 118 S. Ct. 1548 (1998), holds that an adequate written description requires a precise definition, such as by structure, formula, chemical name, or physical properties, "not a mere wish or plan for obtaining the claimed chemical invention." *Elli Lilly*, 119 F.3d at 1566. The Federal Circuit has adopted the standard set forth in the Patent and Trademark Office ("PTO") Guidelines for Examination of Patent Applications under the 35 U.S.C. 112.1 "Written Description" Requirement ("Guidelines"), 66 Fed. Reg. 1099 (Jan. 5, 2001), which state that the written description requirement can be met by

"showing that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics," including, *inter alia*, "functional characteristics when coupled with a known or disclosed correlation between function and structure..." *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 316, 1324-25 (Fed. Cir. 2002) (quoting *Guidelines*, 66 Fed. Reg. At 1106 (emphasis added)). Moreover, although *Elli Lilly* and *Enzo* were decided within the factual context of DNA sequences, this does not preclude extending the reasoning of those cases to chemical structures in general. *Univ. of Rochester v. G.D. Searle & Co.*, 249 Supp. 2d 216, 225 (W.D.N.Y. 2003).

Applicant has failed to provide any structural characteristics, chemical formula, name(s) or physical properties of prostaglandin compounds of formula (I) where R_1 is an aryl or heterocyclic group, aside from a broad recitation and examples that such are contemplated for use in the invention. The size and structural orientation of functional groups on the prostaglandin compounds will influence their ability to bind and interact with cellular receptors. Applicant has failed to adequately disclose the specific aryl and heterocyclic groups contemplated for use in the invention. As such, it is not apparent that Applicant was actually in possession of, and intended to use within the context of the present invention, prostaglandin compounds where R_1 is any aryl or heterocyclic group, at the time the present invention was made.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action

A person shall be entitled to a patent unless—

b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Evans et al. (U.S. Patent No. 6,830,882).

Evans et al. teach "a method for preventing obesity, said method comprising administering to a subject in need thereof an amount of a peroxisome proliferator activated receptor-gamma (PPAR- γ) antagonist effective to block cell differentiation to produce lipid-accumulating cells". See column 9, lines 54-59. Furthermore, Evans et al. teach use of PPAR- γ -selective prostaglandins for said purpose (i.e. to bind to PPAR- γ to block differentiation to produce lipid-accumulating cells). See column 2, last 2 paragraphs.

Therefore, Evans et al. anticipate Claims 1 and 2 of the instant invention.

12. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Pike et al. (U.S. Patent No. 3,888,919).

Pike et al. teach PGE₁ derivatives effective in the treatment of obesity. See last paragraph, column 7 to first three paragraphs, column 8.

Therefore, Pike et al. anticipate Claims 1 and 2 of the instant invention.

Double Patenting

13. It is requested that the Applicant provides a listing of all related co-pending applications and patents.

Conclusion

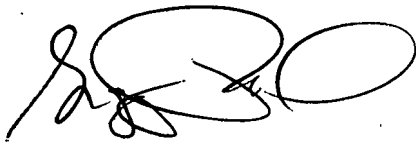
14. Claims 1-9 and 11-13 are rejected.
15. No claims are allowed.
16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregg Polansky whose telephone number is (571) 272-9070. The examiner can normally be reached on Mon-Thur 8:30 A.M. - 7:00 P.M. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

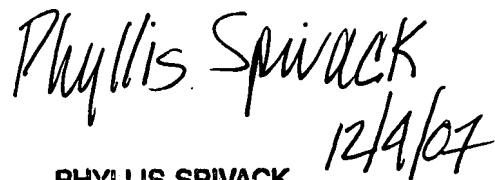
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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A handwritten signature in black ink, appearing to read 'Gregg Polansky', with a large, stylized loop at the end.

Gregg Polansky

A handwritten signature in black ink, appearing to read 'Phyllis Spivack', with a date '12/4/07' written below it.

PHYLLIS SPIVACK
PRIMARY EXAMINER